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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,839	04/20/2006	Roger Alberto	1621 WO/US	2298
Jerad Seurer Mallinckrodt Inc. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, MO 63134			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 04/28/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,839

Applicant(s)

ALBERTO ET AL.

Examiner

D L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34, 37-45 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-53 is/are allowed.
- 6) ☒ Claim(s) 34, 37, 38, 45, 46 and 49 is/are rejected.
- 7) ☒ Claim(s) 47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges the amendment filed 1/14/10 wherein claims 1-33, 35, 36, and 50 were canceled and claim 34 was amended.

Note: Claims 34, 37-49, and 51-53 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENT

2. The Applicant's arguments and/or amendment filed 1/14/10 to the rejection of claims 34, 45, and 47-49 made by the Examiner under 35 USC 102 and/or 112 have been fully considered and deemed persuasive in part for the reasons set forth below.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

Note: It should be noted that Applicant amended the claims to overcome the cited rejection. Thus, the rejection has been excised to that cited in the 103 rejection below.

Scope of Enablement Rejection

The scope of enablement rejection is WITHDRAWN.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 37-45, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention..

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the other definitions for the variables X1, X2, and X3 when only two of the variables are selected from the group consisting of CO, NH3, aromatic heterocycles, thioethers, and isocyanides.. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement,

the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

APPLICANT'S RESPONSE

In summary, Applicant asserts that the written description rejection should be withdrawn because as explained in the specification, it is clear that compounds of claim 34 have the required chemotoxic activity if 'at least two of the ligands in a compound as shown in formula I have been exchanged by guanine or guanosine after 3 days at 37 degrees Celsius with guanine or guanosine being present in a slight excess over rhenium or technetium. In addition, it is asserted that the importance in defining two of the ligands would be obvious to a skilled artisan that the identity of the third ligand is not critical. Furthermore, it is asserted that the invention is not described solely in terms of a method of its making coupled with its function, but based on the details provided throughout the specification detailing the relationship between the structure of the invention and its function.

EXAMINER'S RESPONSE

Applicant's response is not persuasive for the following reasons. First, it should be noted that in independent claim 34, the claim does not set forth any steps or criteria that specifies that at least two of the ligands in a compound of Formula I have been exchanged by guanine or guanosine after 3 days at 37 degrees Celsius with guanine or guanosine being present in a slight excess over rhenium or technetium. While such limitations are present in the specification, Applicant is reminded that it is improper for the Examiner to import claim limitations from the specification into the claims. Applicant's attention is respectfully directed to MPEP 2111.01, Section II. As a result, the Examiner reads the claims and the claims are given the broadest reasonable interpretation. Applicant is respectfully requested to review MPEP 2111. Hence, based on the claims as written, there is no indication in the claim as to what value(s) the third variable in the phrase 'at least two of X1, X2, and X3 are monodentate ligands selected from the group consisting of CO, NH3, aromatic heterocycles, thioethers, and isocyanides' when only two of X1, X2, and X3 are monodentate ligands.

112 Second Paragraph Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 45, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because in independent claim 34, the phrase 'at least two of X1, =X2, and X3 are monodentate ligands selected from the group consisting of CO, NH3, aromatic heterocycles, thioethers, and isocyanides'. In particular, it is unclear what values of the remaining variable from the X1, X2, and X3 grouping Applicant is claiming that is compatible with the instant invention. Since claims 45 and 47-49 depend on claim 34 which is vague and indefinite, then dependent claims are also vague and indefinite.

APPLICANT'S RESPONSE

In summary, Applicant asserts that the 112 second paragraph rejection should be withdrawn because as explained in the specification, it is clear that compounds of claim 34 have the required chemotoxic activity if 'at least two of the ligands in a compound as shown in formula I have been exchanged by guanine or guanosine after 3 days at 37 degrees Celsius with guanine or guanosine being present in a slight excess over rhenium or technetium. Thus, Applicant has concluded that one of ordinary skill would understand that the identity of the third ligand is not critical.

EXAMINER'S RESPONSE

Applicant's response is not persuasive for the following reasons. First, it should be noted that in independent claim 34, the claim does not set forth any steps or criteria that specifies that at least two of the ligands in a compound of Formula I have been exchanged by guanine or guanosine after 3 days at 37 degrees Celsius with guanine or guanosine being present in a slight excess over rhenium or technetium. While such limitations are present in the specification, Applicant is reminded that it is improper for

the Examiner to import claim limitations from the specification into the claims.

Applicant's attention is respectfully directed to MPEP 2111.01, Section II. As a result, the Examiner reads the claims and the claims are given the broadest reasonable interpretation. Applicant is respectfully requested to review MPEP 2111. Hence, based on the claims as written, there is no indication in the claim as to what value(s) the third variable in the phrase 'at least two of X1, X2, and X3 are monodentate ligands selected from the group consisting of CO, NH3, aromatic heterocycles, thioethers, and isocyanides' when only two of X1, X2, and X3 are monodentate ligands. In addition, Applicant is reminded that based on the requirements of 35 USC 112 first paragraph, the claims should be described in a matter such that they convey to one skilled in the art at the time the application is filed that Applicant has possession of the claimed invention. Thus, the rejection is deemed proper.

NEW GROUNDS OF REJECTION

103 Rejection

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

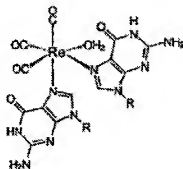
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 34, 37, 38, 45, 46, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Zobi et al (Inorg. Chem, 2003, Vol. 42, pages 2818-2820).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).



Zobi et al disclose a compound, (seepage 2818, Scheme 1), that is identical to Applicant's Compound 3. In particular, this compound fulfills the requirements of the metal tricarbonyl compound when at least two of X1, X2, and X3 are monodentate aromatic heterocyclic ligands. Thus, both Applicant and Zobi et al disclose a metal tricarbonyl compound. While the prior art does not specifically state that the compound treats cancer, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the prior art may be used to treat cancer because in the background of the invention (page 2818, left column), it is disclosed that tricarbonylrhenium complexes have been recently described to efficiently suppress the growth of solid and suspended tumor cell lines. In addition, on page 2820, concluding paragraph, it is disclosed that the rhenium compounds have cytotoxicity characteristic and may be used for chemo- or radiotherapeutic purposes.

ALLOWABLE CLAIMS

6. Claims 51-53 are allowable over the prior art of record because the prior art neither anticipates nor renders obvious the compounds of independent claim 51.

CLAIM OBJECTIONS

7. Claims 47 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: It should be noted that the claims are only distinguished over the art as they read on Applicant's Compound 3 coupled to a targeting moiety.

WITHDRAWN CLAIMS

8. Claims 39-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

April 25, 2010